

AUG 23 1999

K 992644

**Special 510(k) Summary
for
SIDEXIS Digital Radiography Imaging System**

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstraße 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 3294

Date Prepared: August 5, 1999

2. DEVICE NAME

Proprietary Name: SIDEXIS Digital Radiography Imaging System
Common/Usual Name: Digital X-ray Imaging System
Classification Name: Accessory to Extraoral Source X-ray System

3. PREDICATE DEVICE

SIDEXIS Digital Radiography System – K972168

4. INTENDED USE

The SIDEXIS is a digital imaging system intended to replace conventional radiographic film for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

5. DEVICE DESCRIPTION

SIDEXIS consists of intraoral and extraoral digital X-ray sensors, image acquisition boards, and software to be installed into an IBM-compatible personal computer. Accessories to be used with the intraoral sensors include holders and hygienic

covers. Use of the SIDEXIS differs from conventional X-ray imaging only due to the use of the PC and the X-ray sensors. The X-rays are produced using the customary method of the intraoral or extraoral X-ray system, however, an electronic, radiation sensitive sensor element is used in place of the conventional film carrier. The radiation is then converted into electronic signals that are relayed through cables connecting the sensor to the PC directly or through a network.

The SIDEXIS can be used with:

- Intraoral sensors and an intraoral dental X-ray device (e.g., Heliodont DS); and
- Panoramic or cephalometric sensors and an extraoral source X-ray device (e.g., Orthophos 3DS, DS, or DS Ceph).

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The SIDEXIS that is the subject of this 510(k) premarket notification is a modification of the SIDEXIS previously cleared for marketing under K972168. The modified SIDEXIS has the same intended use and principles of operation as the original SIDEXIS. Modifications are summarized as follows:

- Additional sensors are available
- Additional image acquisition boards are available to interface between the sensors and the computer.
- The system is offered in a variety of kit configurations to allow for installation in a personal computer system or in an adapter box for wall mounting, which can be used in a network system
- The SIDEXIS can now be used under the Windows® 98 and Windows® NT operating systems.
- The recommended computer platform has been upgraded to a Pentium-based system.

A hazard analysis, validation testing, and Declaration of Conformity to Design Controls were submitted to support the substantial equivalence of the modified to the original SIDEXIS Digital Radiography Imaging System.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 1999

Sirona Dental Systems GMBH
C/o Sheila Hemeon-Heyer, Esq., RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

RE: K992644
SIDEXIS Digital Radiography Imaging Dental System
Dated: August 5, 1999
Received: August 6, 1999
Regulatory Class: II
21 CFR 872.1800/Procode: 90 MUH

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

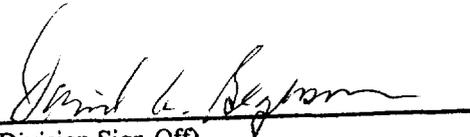
Device Name: SIDEXIS DIGITAL RADIOGRAPHY IMAGING SYSTEM

Indications For Use:

The SIDEXIS is a digital radiography imaging system intended to replace conventional radiographic film for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K992644

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)